



SHARE-TAVI 1-year results

– how do we compare?

E Schaafsma, J Scherman, H Weich, M Ntsekhe
On behalf of the SHARE TAVI Investigators

Potential conflicts of interest

Speaker's name: Elizabeth Schaafsma

I do not have any potential conflict of interest

Background

- SA Heart saw need for independent registries >10years ago
- Locally relevant data to inform policies and benchmark against best-practice guidelines
- Evolution of initial national registries
- Project-based niche registries
- Condition or intervention-specific registries
- SHAREd resources and datasets, voluntary participation
- Constrained-resource economy
- South African Heart Association Registries
- Commitment to improving patient care – shared experience

Background / Study objective

- SHARE pilot study - 3 year plan with Proof of concept
- Although the results of transcatheter aortic valve implantation (TAVI) are well documented for developed countries, the uptake and outcomes in emerging and threshold economies are less well explored.
- The aim of this study therefore was to report on the first clinical outcomes from the national SHARE TAVI registry (South African Heart Association Registries – TAVI registry).

Methods

- The SHARE - TAVI registry is a prospective observational multicentre registry with Ethics approval from 2 Universities SUN and UCT.
- It is designed to capture data for all patients undergoing TAVI across South Africa in a dedicated web-based database.
- The registry was launched in September 2014.
- Procedural, 30-day and 1-year outcomes are reported as defined by the VARC-2 criteria

Location of sites

- Flora
- Groote Schuur
- Panorama
- St Augustine's
- Sunninghill
- Tygerberg
- Unicare/Universitas
- Union
- Unitas
- Vergelegen
- Vincent Pallotti



- All 11 of the centres performing TAVI in South Africa are actively capturing data into the registry.
- 7 sites per <20 implants/year
- 15% of procedures in 3 State teaching facilities



Site details

Practice name Test site (TAVI)
Practice number
Telephone
Fax

Patient details

Name Ms Karen Test-Scott
Account # B52
Gender Female
Ethnic classification Caucasian (White)
Language English
Date of birth 1971-06-17
ID # 7106170141388
Medical aid scheme DISCOVERY HEALTH MEDICAL SCHEME
Medical aid # 480 8080378
Phone (mobile) 083 603 7709
Phone (home)
Phone (mobile) 083 603 7709
Phone (home)
Phone (work)
Physical address
Postal address

Clinical evaluation

Clinical information

Consultation date: 2017-03-23
Age at consultation: 45

History and risk factors

Cardiac history

Prior CABG: No

Other history

Hypertension: Yes

Pre-operative special investigations

Echo (TTE or TOE)

24th March, 2017

Page 1 of 2

This patient was entered into the SHARE II TAVI registry

TAVI



Shared experience, improved patient care



Mean gradient across aortic valve (mm Hg): 80

Aortic valve area (cm²): 1.1

Ejection fraction (%): 26

Associated valvular lesions

Mitral stenosis: Trivial

Heart team meeting decision

Decision date: 2017-03-21

Final decision: TAVI

TAVI evaluation

Risk profile

Predicted operative risk: Medium

Log EuroScore %: 33.15

STS Score %: 19

Contra-indication to surgery: Yes

Reason for contra-indication to surgery

Porcelain aorta: Yes

24th March, 2017

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Shared experience, improved patient care



Participation after Funding Applied = **No**

| Exit after funding application | n=54 |
|---|-------------|
| Funding application process mortality | (14) |
| Mortality – Prior to approved procedure | 3 |
| Mortality - while waiting for funding response | 11 |
| | |
| Funding declined | (22) |
| Alive | 11 |
| Mortality | 11 |
| | |
| Other exit reason (e.g. patient declined, condition deteriorated, referred for surgery, other) | (18) |
| Alive | 13 |
| Mortality | 3 |
| Other exit reason Aborted procedure | 2 |

Mortality of patients in application process or declined funding – 41%

Participation after Funding Applied

Yes



| TAVI Funding n= 390 | % |
|--|------------|
| Blank | 26 |
| Medical aid approval - Full amount | 36 |
| Medical aid approval - Partial amount | 26 |
| Medical aid declined - Patient Self-funded | 3 |
| State-funded | 10 |
| | |
| AWAITING FUNDING DECISIONS April 2015 - Present | 108 |
| Median wait for funding decision (was 180d) | 103 d |
| Median days to procedure from Consult | 83d |

Patients

Study period: September 2014 to October 2017

| | | |
|-----------------------------------|------------------------|--|
| Patients enrolled into registry | n = 558 | |
| Approved for TAVI by a Heart Team | n = 545 | Awaiting Heart Team decision (n=5) Reasons for exit (n=8) 6 referred for conventional surgery 2 referred for medical treatment |
| Patients proceeding to TAVI | n = 390 (study cohort) | Reasons for not proceeding (n=155) 99 Awaiting funding decisions 8 Approved awaiting TAVI date 11 Mortality while waiting for decision 3 Mortality, funding approved, before TAVI 11 Mortality after funding declined 8 Funding declined 3 Patient declined 12 Other exit reason (mortality in 3) 2 Aborted Procedure |

Study cohort (n=390)

| | | | |
|-----------------|--------------------|---------------------|-----------------|
| Mean age: | 80.35 ±7.155 years | Male gender: | 52.3.0% (n=204) |
| Mean STS score: | 6.34 ±5.82 | Mean Log Euroscore: | 21.84 ±14.24 |

Contra-indications for surgery:

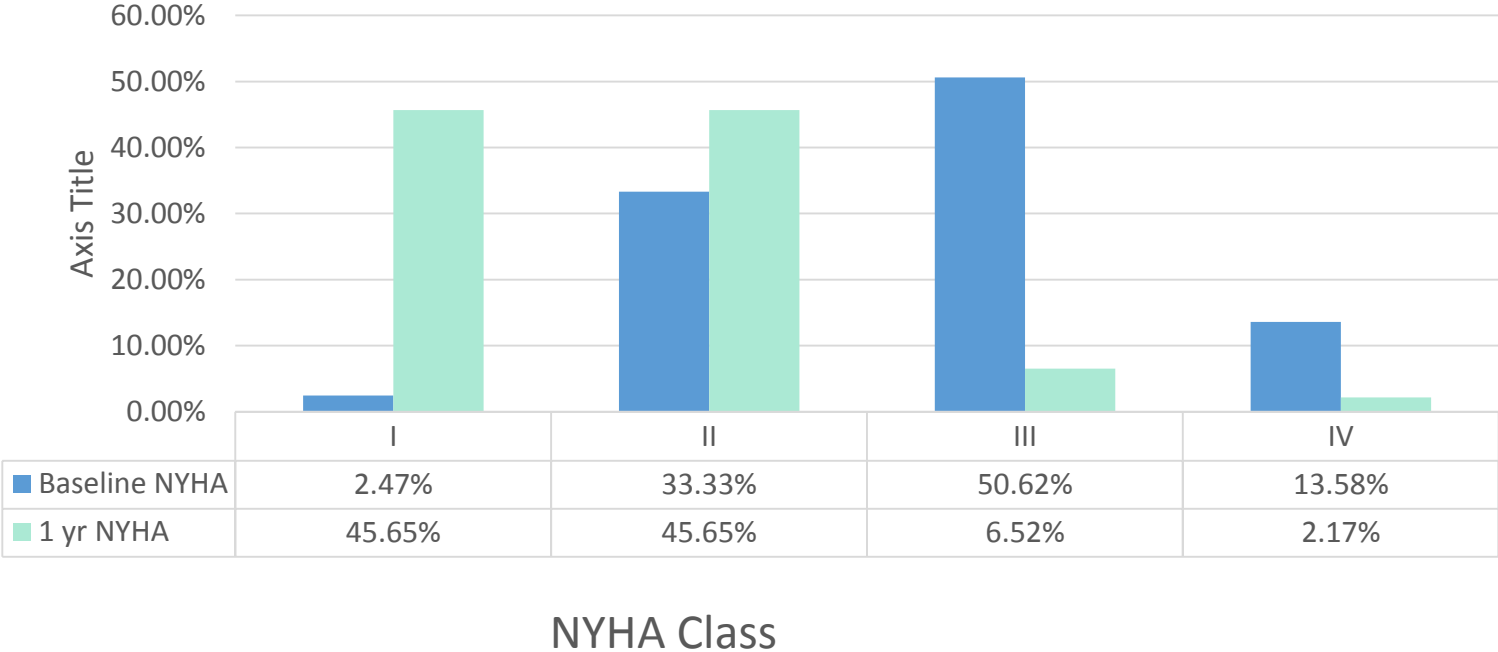
| | |
|-------------------|-----------------|
| Frailty | 34.87 % (n=136) |
| Porcelain aorta | 7.18 % (n=28) |
| Patent LIMA graft | 12.31 % (n=48) |
| Hostile thorax | 2.31 % (n=9) |

Results 4: Procedural Outcomes 30-days (n = 370)

- STS Risk of Mortality - 6.38 %
- Early mortality all-cause 4.9%
 - Intra-procedural : 9
 - Post-op <72hrs : 4
 - Index hospitalization: 3
 - Discharge to 30d: 2

| | |
|----------------------|------|
| SHARE | 4.9% |
| SOURCE | 8.5% |
| PARTNER A | 6.5% |
| GARY | 5.6% |
| CoreValve US pivotal | 3.4% |
| PARTNER 2 | 4% |

Results 5: 1-Year Outcomes



Results 6: Procedural Outcomes 1-Year Mortality

- 181 patients with 1-Yr Follow Up
- 33 deaths all-cause = 18%
- Cardiac mortality 11.5%
- Non-cardiac mortality 6.7%
 - mostly malignancy or pneumonia

1-year All-Cause Mortality

| | |
|----------------------|-------------|
| SHARE | 18 % |
| PARTNER A | 24 % |
| SOURCE | 24 % |
| CoreValve US pivotal | 14 % |
| PARTNER 2A | 12 % |

Conclusions

- TAVI provides good early and mid-term outcomes for appropriately selected patients suffering from severe aortic stenosis.
- In resource-constrained economies, funding remains a major challenge for its appropriate and widespread use. Reporting outcomes through national registries could aid in addressing these constraints.

Acknowledgements

- This presentation is undertaken on behalf of all the Investigators and team members at the following sites:
- Flora
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Results 1: Procedural Outcomes

| Procedural outcomes (n=370) | |
|--|-----------------|
| Transfemoral access | 90.94 % (n=206) |
| Overall procedural success | 93 % |
| Immediate peri-procedural complications (≤ 72 hours) | |
| Mortality | 3.51 %, n=13 |
| Myocardial infarction | 0.72 % n=2 |
| Stroke | 0.01 % n=2 |
| Bleeding complications | 6.5 % n=24 |
| Vascular complications | 7.6 % n=28 |
| Valve in Valve | 4.6 % n=17 |

Results 2: Procedural Outcomes

| Procedural outcomes (n=370) | | |
|-----------------------------|-----------------------------|-------------------------|
| | Transfemoral access (n=335) | Non-Transfemoral (n=35) |
| Procedural Success | 93.9% | 93.9% |
| Mean STS score % | 6.56 | 4.87 |

Results 3: Early Outcomes (\leq 30d)

| Early Outcomes (n=370) | |
|---|----------------------|
| Mean ICU stay | 2.38 \pm 1.83 days |
| Mean high care stay | 1.65 \pm 1.76 days |
| Mean ward stay | 3.03 \pm 2.30 days |
| New permanent pacemaker implantation | 5.02% (n=13) |
| CVA | 3.86% (n=10) |
| Cardiac related re-admissions (\leq 30d) | 3.09% (n=8) |
| 30d all-cause mortality | 4.9% (n=18) SHARE |